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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,920	04/03/2001	Ronald G. Udell	40524-SGTI	3656
25763	7590	11/03/2005		
DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT 50 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402-1498			EXAMINER WINSTON, RANDALL O	
			ART UNIT 1655	PAPER NUMBER

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,920

Applicant(s)

UDELL ET AL.

Examiner

Randall Winston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-3 and 18-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement is made of receipt and entry of the amendment filed on August 17, 2005.

Claims 19-31 are under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-31 stand rejected under 35 U.S.C. 103(a) as unpatentable over Matsuyama (US 6485760) in view of Hunger (US 3886940), Mcpeak (US 6303586), LaGrone (US 6407068), Matsutani et al. (US 5552427), Shanmuyasundam et al. (US 5980902) .

Applicant argues Hunger, a secondary reference, fails to remedy the deficiencies of Matsuyama. Hunger discloses that the capsule is a two piece capsule, not a uniform, unitary soft gelatin capsule as utilized in the present invention. Therefore, neither Matsuyama or Hunger as well as none of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a soft gel capsule that encapsulates liquified corosolic acid could be prepared by the claimed method. Applicant's argument is not found persuasive because applicant's claims 19-31 do not claim a soft gel capsule as a unitary soft

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gelatin capsule. However, even if applicant did claim its soft gel capsule as a unitary soft gelatin capsule, it would still be obvious to modify Matsuyama's oral composition teachings to include Hunger's beneficial oral soft gel teaching because it is beneficial to utilize a soft gel capsule which melt or disintegrate at internal body temperatures because the soft gel capsule is able to easily dissolve within the body when administered orally. Furthermore, as the examiner explained in his non-final office action of 05/17/2005, all of the combined references, alone or in combination, teach or suggest, provide a motivation or an expectation of creating the claimed invention. For example, Matsuyama teaches an oral composition comprising corosolic acid for an increase in or lowering of blood sugar levels in a patient. Hunger beneficially teaches (see, e.g. column 2 lines 39-45) that soft gelatin used for oral capsules melt or disintegrate at internal body temperatures. Mcpeak et al. beneficially teach rice bran oil (i.e. the rice bran is in liquid form) to control blood glucose levels. (see, e.g., column 7 lines 52-56). LaGrone beneficially teach silica for the prevention of diabetes whereas silica would intrinsically control blood glucose levels when preventing diabetes. (see, e.g., column 4 lines 11-14). Shanmyasundam et al. beneficially teach an extract of *Gymnema sylvestre* for controlling blood sugar to prevent obesity. (see, e.g., column 3 lines 16-20). Matsutani et al. beneficially teach tablets were polished with yellow bees wax to give coated tablets. (see, e.g., column 20 lines 9-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Matsuyama's oral composition teachings to include Hungers 's beneficial oral soft gel teachings (e.g. it is beneficial to utilize a soft gel

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capsule because a soft gel capsule is able to easily dissolved within the body when administered orally) (note: the yellow bees wax taught by Matsutani is being utilized to coat the soft gel capsule) and also to include other beneficial teachings taught by Mcpeak, LaGrone, Shanmuyasumdam whereas Mcpeak, LaGrone, Shanmuyasumdam active ingredients are each being utilized for the maintaining or lowering of blood glucose levels in humans to obtain an improved claimed soft gel capsule composition for the administration of corosolic acid, rice bran oil, silica, yellow bee's wax, extract of *Gymnema sylvestre*, in a soft gel capsule for the maintaining or lowering blood sugar levels in humans. Furthermore, the adjustment of other conventional working conditions (e.g. the amount of corosolic acid contained within the soft gel capsule), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please Note that patentability of a product (i.e. the claimed soft gel capsule) does not depend upon its method of production (i.e. heating the rice bran oil, continuously stirring the mixture, the corosolic acid is under a vacuum, the mixture is blended with nitrogen, the corosolic acid is produced by 1% Corosolic acid alcohol extracted from *Lagerstroemia Speciosa L.*). If the product in the product-by-process claim is the same as or obvious from a product of the prior art, then the claim is

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unpatentable even though the prior art product was made by a different process" (see, e.g. MPEP 2113).

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan D. Coe
10-24-05

SUSAN COE
PRIMARY EXAMINER